DETAILED ACTION

1.   The following is a **Non-Final Office Action** in response to the Request for

Continued Examination filed on 08 February 2011. Claims 1, 8, 9 and 12 have been

amended. Claim 26-29 are newly added. Claims 1-29 are pending in this application.

Response to Arguments

2.   Applicant's arguments, see Remarks pgs. 12-14, filed 08 February 2011 with

respect to the rejection of claims 1-7 under 35 U.S.C. 103(a) have been fully considered

and are persuasive. The rejection of claims 1-7 have been withdrawn.

3.   Applicant's arguments, see Remarks pgs. 12-14, filed 08 February 2011, with

respect to the rejection of claim 8 under 35 U.S.C. 103(a) have been considered but are

moot in view of the new ground(s) of rejection.

4.   Applicant's arguments, see Remarks pgs. 14-18, filed 08 February 2011, with

respect to the rejection of claims 12-25 under 35 U.S.C. 103(a) have been fully

considered but they are not persuasive.

5.   With respect to the Applicant's arguments that the prior art fails to teach,

"thereby assigning the set of operating parameters identified by the user-defined

identifying name to the delivery program"; the Examiner has further clarified the

rejection of claim 12 with respect to this limitation on pages 8-10, paragraph 13 of this

Office Action.

6.   Claims 8, 12-25, 28 and 29 stand rejected under 35 U.S.C. 103(a) as set forth

below.

Claim Rejections - 35 USC § 103

7.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented
> and the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

8.   Claims 8, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable

over U.S. Patent Publication No. 2003/0114836 A1 (hereinafter Estes) in view of U.S.

Patent Publication No. 2003/0069650 A1 (hereinafter Karmiy) in further view of U.S.

Patent No. 5,814,015 (hereinafter Gargano) and U.S. Patent No. 5,719,761 (hereinafter

Gatti).

9.   As per claim 8, Estes teaches a method of operating a pump (Fig. 1, element

100), the pump having a memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) and a

pump mechanism (pg. 3, par. [0029]), the method comprising:

receiving from a computer, a plurality of data sets, each data set in the plurality

of data sets containing a plurality of operating parameters (Fig. 3A, element 300; Fig. 2,

elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6,

par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the

event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time

change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7,

par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus

estimator 128 in calculating an insulin dosage"),

storing the plurality of data sets in memory (pgs. 3-4, par. [0035] and Fig. 1,

element 106);

selecting one of the plurality of data sets (pg. 8, par. [0008] and Fig. 6, i.e.

SUSPEND, BOLUS, BASAL), assigning the set of operating parameters (pg. 6, par.

[0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus:

5.7U, Time Display: 24 Hr., Beep Volume: 3) to the delivery program (pg. 8, par.

[0073] and Fig. 6, BOLUS DELIVERY); and

running the delivery program wherein the delivery program executes the

operating parameters in the selected one of the plurality of data sets, the operating

parameters defining a delivery schedule for controlling the pump mechanism (pg. 8,

par. [0073] and Fig. 6, BOLUS DELIVERY).

Estes teaches a method substantially the same as claimed but does not expressly

teach the delivery program upon selection of the user-defined identifying name (pg. 7,

par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); wherein each data set in the

plurality of data sets contains the same type of operating parameters; and at least two

of the data sets contain different values for the same type of operating parameter.

Karmiy teaches wherein each data set (Fig. 1, element 112a-112c; i.e. one of a

plurality of procedures containing data) in the plurality of data sets (pg. 2, par. [0026],

pg. 6, par. [0062] and Fig. 1, element 112a-112c; i.e. a plurality of procedures

containing data) comprising the same type of operating parameters (pg. 3, par. [0034]

and [0035] and Fig. 3, element 304h and 304i; i.e. an alarm value and engineering

units) and at least two of the data sets (pg. 2, par. [0026] and Fig. 1, element 112a-

112c) contain different values for the same type of operating parameter (pg. 3, par.

[0034] and pg. 5, par. [0058] and Fig. 3, element 304h; i.e. different procedures

contain different values for the same type of operating parameters via editing/creating

and saving parameters of one procedure without effecting another procedure's

parameters).

Karmiy does not expressly teach the delivery program upon selection of the user-

defined identifying name.

Gargano teaches the delivery program upon selection of the identifying name

(col. 6, lines 19-30; i.e. selection the "drug name" initiates a delivery program).

Gargano does not expressly teach a user-defined identifying name.

Gatti teaches a user-defined identifying name for an infusion pump (col. 8, lines 30-39).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include wherein data sets comprising the same type of operating parameters and at least two of the data sets contain different values for the same type of operating parameter to provide an improved and efficient techniques for generating instruction to control a device by providing users with the ability to directly edit cells of a table (Karmiy: pg. 1, par. [0004] and pg. 8, par. [0078] and [0079]); the delivery program upon selection of the identifying name to provide a method of customization entry of drug information for a wide range of drug types and chemistries (Gargano: col. 1, lines 28-34); and a user-defined identifying name for an infusion pump to provide unique identifying name to a new configuration to avoid having mix of configurations with the same name (Gatti: col. 8, lines 40-44).

10. As per claim 28, neither Estes nor Karmiy expressly teach the user-defined identifying name is selected from a list of preprogrammed names.

Gargano teaches selection of the identifying name is selected from a list of preprogrammed names (col. 6, lines 19-30; i.e. selection the "drug name" initiates a delivery program).

Gargano does not expressly teach a user-defined identifying name.

Gatti teaches a user-defined identifying name for an infusion pump (col. 8, lines 30-39).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes in view of Karmiy to include selection of the identifying name is selected from a list of preprogrammed names to provide a method of customization entry of drug information for a wide range of drug types and chemistries (Gargano: col. 1, lines 28-34); and a user-defined identifying name for an infusion pump to provide unique identifying name to a new configuration to avoid having mix of configurations with the same name (Gatti: col. 8, lines 40-44).

11.   As per claim 29, Estes, Karmiy, nor Gargano expressly teach wherein the user-defined identifying name is generated by a user.

Gatti teaches the user-defined identifying name is generated by a user (col. 8, lines 30-39).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes in view of Karmiy in further view of Gargano to include the user-defined identifying name is generated by a

user to provide unique identifying name to a new configuration to avoid having mix of
configurations with the same name (Gatti: col. 8, lines 40-44).

12.   Claims 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over
Estes in view of Gargano in further view of Gatti.

13.   As per claim 12, Estes teaches a method of operating an infusion pump (Fig. 1,
element 100) for delivering a therapeutic agent into the body of a user (pg. 3, par.
[0029]), the infusion pump being programmable (pgs. 3-4, par. [0034] and [0035] and
Fig. 2, element 132) and including memory (pgs. 3-4, par. [0035] and Fig. 1, element
106), the infusion pump being programmed to run a delivery program (pgs. 3-4, par.
[0034] and [0035] and Fig. 2, element 132), the delivery program controlling the
infusion pump to deliver the therapeutic agent according to a delivery schedule (pg. 3,
par. [0032]-[0034], pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY), the method
comprising:

storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106),
the data set including a set of operating parameters defining a delivery schedule (pg.
6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max
Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), at least one of the operating
parameters being a identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at
12:57 AM); and

assigning the set of operating parameters (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3) to the delivery program (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY);

running the delivery program (pg. 8, par. [0073] and Fig. 6), the delivery program executing the set of operating parameters thereby controlling the infusion pump to deliver the therapeutic agent according to the delivery schedule defined by the set of operating parameters (pg. 6, par. [0057] and [0059]).

Estes teaches a method substantially the same as claimed but does not expressly teach selecting one user-defined identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected user-defined identifying name (pg. 6, par. [0057] and [0059]).

Gargano teaches a field for the selection of an identifying a name (col. 11, lines 40-47; i.e. the "drug name"); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected identifying name (col. 6, lines 19-30; i.e. selection the "drug name" initiates a delivery program).

Gargano does not expressly teach a user-defined identifying name.

Gatti teaches a user-defined identifying name for an infusion pump (col. 8, lines 30-39).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a field for the selection of an identifying a name; and running the delivery program wherein the delivery program executes the operating parameters identified by the selected identifying name to provide a method of customization entry of drug information for a wide range of drug types and chemistries (Gargano: col. 1, lines 28-34); and a user-defined identifying name for an infusion pump to provide unique identifying name to a new configuration to avoid having mix of configurations with the same name (Gatti: col. 8, lines 40-44).

14.   As per claim 13, Estes teaches as set forth above downloading the data set to the pump from a computer (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

15.   As per claim 14, Estes teaches as set forth above the act of storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) further comprising storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5,

Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from

carbohydrate consumption events from the event marker table that have been logged

by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr

format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these

events can be taken as inputs to the bolus estimator 128 in calculating an insulin

dosage").

16.   As per claim 15, Estes teaches as set forth above to generating a menu, the

menu including at least one menu item corresponding to one of the user-defined

identifying names; and the act of selecting the user-defined identifying name further

comprising selecting the menu item (pg. 8, par. [0073] and Fig. 6, element "Main

Menu").

17.   As per claim 16, Estes teaches as set forth above the act of storing a data set in

the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) further comprising storing

two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106)

includes storing a plurality of data sets in memory, each data set including a set of

operating parameters defining a separate delivery schedule (Fig. 3A, element 300; Fig.

2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg.

6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from

the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the

time change is displayed in either 12 or 24 hr format depending on user's settings"; pg.

7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus

estimator 128 in calculating an insulin dosage").

18.   As per claim 17, Estes teaches as set forth above to generating a menu includes

generating a menu having at least one menu item corresponding to a user-defined

identifying name from one data set and at least one menu item corresponding to a

user-defined identifying name from another data set (pg. 8, par. [0073] and Fig. 6,

element "Main Menu").

19.   As per claim 18, Estes teaches as set forth above to the execution of the delivery

program from the set of operating parameters in one data set to the set of operating

parameters in another data set (pg. 8, par. [0074]).

20.   As per claim 19, Estes teaches an infusion pump (pgs. 2-3, par. [0027] and Fig.

1, element 100) comprising:

        a pump mechanism (pg. 3, par. [0029]);

        memory storing a data set (pgs. 3-4, par. [0035] and Fig. 1, element 106), the

data set including a set of operating parameters defining a delivery schedule (pg. 6,

par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max

Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), at least one of the operating

parameters being a identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at

12:57 AM); and

a processor (pg. 3, par. [0034]; e.g. PC, laptop) arranged to control the pump

mechanism and in data communication with the memory (pgs. 3-4, par. [0034]), the

processor being programmed to assign the set of operating parameters (pg. 6, par.

[0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus:

5.7U, Time Display: 24 Hr., Beep Volume: 3) to the delivery program (pg. 8, par.

[0073] and Fig. 6, BOLUS DELIVERY) and to execute the set of operating parameters

thereby controlling the pump mechanism to deliver the therapeutic agent according to

the delivery schedule (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY).

Estes teaches a method substantially the same as claimed but does not expressly

teach the delivery program upon selection of the user-defined identifying name (pg. 7,

par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

Gargano teaches the delivery program upon selection of the identifying name

(col. 6, lines 19-30; i.e. selection the "drug name" initiates a delivery program).

Gargano does not expressly teach a user-defined identifying name.

Gatti teaches a user-defined identifying name for an infusion pump (col. 8, lines

30-39).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include the delivery program upon selection of the identifying name to provide a method of customization entry of drug information for a wide range of drug types and chemistries (Gargano: col. 1, lines 28-34); and a user-defined identifying name for an infusion pump to provide unique identifying name to a new configuration to avoid having mix of configurations with the same name (Gatti: col. 8, lines 40-44).

21.   As per claim 20, Estes teaches set forth above a data port (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop), the processor being further arranged to control downloading of the data set and storage of the data set into the memory (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

22.   As per claim 21, Estes teaches as set forth above the memory further storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100,132; 0035, lines 1-7; Fig. 5, Alarm/Event Marker Table; Page 6, [0060], lines 1-6, i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; Page 7, [0063], lines 1-13, i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; [0064], lines 13-15, i.e., "At least some of these

events can be taken as inputs to the bolus estimator 128 in calculating an insulin

dosage").

23.   As per claim 22, Estes teaches as set forth above the processor being further

programmed to:

        generate a menu, the menu including at least one menu item corresponding to

one of the unique identifying names, selecting the menu item being at least one step in

beginning execution of the delivery program (pg. 8, par. [0073] and Fig. 6, element

"Main Menu").

24.   As per claim 23, Estes teaches as set forth above the memory further storing two

or more data sets (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set

including a set of operating parameters defining a separate delivery schedule (Fig. 3A,

element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event

Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate

consumption events from the event marker table that have been logged by the user";

pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending

on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken

as inputs to the bolus estimator 128 in calculating an insulin dosage").

25.   As per claim 24, Estes teaches as set forth above the processor being further

programmed to generate a menu, the menu including at least one menu item

corresponding to a user-defined identifying name from one data set and at least one

user-defined identifying name from another data set (pg. 8, par. [0073] and Fig. 6,

element "Main Menu").

26.   As per claim 25, Estes teaches as set forth above the processor being further

programmed to switch execution of the delivery program from the set of operating

parameters in one data set to the set of operating parameters in another data set (pg.

8, par. [0074]).

Allowable Subject Matter

27.   Claims 1-7, 9-11, 26 and 27 are allowable over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Jennifer L. Norton whose telephone number is

(571)272-3694. The examiner can normally be reached on Monday-Friday between

9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Albert DeCady can be reached on 571-272-3819. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

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800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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